DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973)
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gs1990

February 1, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph Fontanetta
President & CEO
Diopsys, Inc.
16 Chapin Road, Suite 911
P.O. Box 672
Pine Brook, New Jersey 07058

05-NWJ-09

Dear Mr. Fontanetta:

Between August 18 and September 2, 2004, FDA investigators conducted an inspection of your establishment formerly located in Metuchen, NJ, and confirmed that your firm manufactures pediatric Visual Evoked Response Photic (VEP) stimulators, known as the ENFANT™ Vision Testing System. These pediatric VEP stimulators are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Management has not assured that an adequate and effective quality system was implemented to fulfill the requirements of 21 CFR 820. Specifically,

    a. There was no quality plan which defined the quality practices, resources, and activities relevant to your devices (21 CFR 820.20(d)).
    b. Quality system procedures were not finalized and implemented (21 CFR 820.20(e)).
    c. Management with executive responsibility did not review the suitability and effectiveness of your firm's quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements

of the Quality System regulations and the specific requirements of your policy and objectives. (21 CFR 820.20(c)). In fact, you did not have any management structure in place to begin to fulfill this responsibility.

d. Management had not appointed a representative with authority and responsibility to assure that the quality system requirements were effectively established and maintained and to report to management on the performance of the quality system (21 CFR 820.20(b)(3)).

2. Procedures were not established and maintained for implementing corrective and preventive actions as outlined in 21 CFR 820.100 (a), nor were these required activities and their results documented, as required by 21 CFR 820.100 (b).

Moreover, the Act requires manufacturers of medical devices to obtain marketing approval or clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that newly-introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in the United States. According to our records, you have not obtained marketing approval or clearance for the ENFANT™ Vision Testing System. During the inspection, you stated to the FDA investigator your belief that the device known as The [redacted] which was determined by FDA to be substantially equivalent and cleared for marketing under [redacted] was included in your firm's acquisition of [redacted] However, because of significant changes you have made to the design of The [redacted] the premarket clearance for that device does not apply to the resulting new product, ENFANT™ Vision Testing System. Changes made during the development of ENFANT™ Vision Testing System include re-writing the system software in [redacted] to operate on a [redacted] replacing the original [redacted] version of the software.

This change represents a major modification that could significantly affect the safety or effectiveness of your device. Under FDA Regulations at 21 CFR 807.81(a)(3)(i), any change that could significantly affect the safety or effectiveness of a device, including significant changes to the design, material, chemical composition, energy source, or manufacturing process, requires the submission of a premarket notification (also referred to as a "510(k)") in accordance with Section 510(k) of the Act. Because you did not submit a 510(k) to the agency prior to introducing the ENFANT™ Vision Testing System into commercial distribution, this device is misbranded under Section 502(o) of the Act. Until you submit a 510(k) and FDA reviews it and notifies you that your device is substantially equivalent to another legally marketed device, the ENFANT™ Vision Testing System is also adulterated under Section 501(f)(1)(B) of the Act because the law requires, and you do not have, an approved premarket approval application (PMA) that shows your new device is safe and effective. For a product requiring premarket review before marketing, the notification required by Section 510(k) of the Act is deemed to be satisfied when a PMA is pending before the agency [21 CFR 807.81(b)].

Diopsys, Inc.
Metuchen, NJ 08840
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Your Enfant™ Vision Testing System is also misbranded under 502(o) of the Act, in that the device was not included in a list required by Section 510(j).

FDA's inspection also revealed that this device is misbranded under Section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as required by Section 519 respecting the device and the Medical Device Reporting (MDR) regulation, Title 21 CFR, Part 803. Significant deviations include, but are not limited to, failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. Our inspection found that your firm had no MDR procedures at all.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

The specific violations noted in this letter and on the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations found by the FDA. You also must promptly initiate permanent corrective and preventive action for your quality system.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market approval applications (PMAs) for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for certificates to foreign governments will be granted until the violations related to the subject devices have been corrected.

We have received your letter of response to the FDA 483, dated December 29, 2004; it will be made part of our official file. After reviewing the information provided, we have the following questions and comments.

1) You have not addressed the listing of your devices although you were informed of this requirement during the inspection.
2) We acknowledge the receipt of your device establishment registration form.
3) Although subsequent to the date of FDA's inspection, you filed a new 510(k) for the ENFANT device, we remind you that until FDA reviews this submission and determines that the device is substantially equivalent to an existing device, it is still considered to be adulterated under Section 501(f)(1)(B) of the Act and may not be distributed. Units of the device that were distributed prior to the filing of the 510(k) are also misbranded under section 502(o), as explained previously.
4) Your response did not include your implemented Quality Manual or any applicable SOPs, therefore we cannot make an adequate assessment of your corrective actions based on the response. The Draft Quality Manual and Draft SOPs provided to the investigators during the inspection did not appear to be sufficient to assure compliance with the Act and the requirements of the

Quality System Regulation. Your draft documents and outline of quality responsibilities appeared to be focused primarily on ISO standards rather than 21 CFR Part 820 requirements.

5) Your response indicated that the devices have been tested according to IEC 60601-1. You made this same statement during the inspection, yet no documentation was available to confirm the testing. You have not included any documentation with your response either, therefore we cannot assess the adequacy of the correction.
6) Your response indicates that new labeling was created and reviewed by an outside firm during their ISO reviews. You did not include copies of the labeling with your response, nor did you state whether or not the labels had been reviewed and deemed acceptable to meet all FDA requirements.

For these reasons, we do not find your written response to be adequate at this time.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to Sarah A. Della Fave, Compliance Officer, U.S. Food and Drug Administration, New Jersey District, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

Sincerely,

Ray Abrahams for

Douglas I. Ellsworth
District Director
New Jersey District